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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/039,799

01/04/2002

J. Bruce Pitner

P-5504

9195

46851

7590

06/13/2005

DAVID W. HIGHET

BECTON, DICKINSON AND COMPANY

1 BECTON DRIVE, MC110

FRANKLIN LAKES, NJ 07417

EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/039,799

Applicant(s)

PITNER ET AL.

Examiner

Roy Teller

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/05 has been entered.

Claims 1 and 3-13 are pending.

### ***Claim Rejections - 35 USC § 112***

Claims 1, 3-7 and 12-13 are/stand rejected under 35 U.S.C. 112, first paragraph for the reasons of record which are restated below.

The instant invention is drawn to a biosensor comprising at least one mutated binding protein and at least one thiol group and at least one sensor surface which provides a detectable signal resulting from a change in refractive index when the mutated binding protein binds to analyte.

With respect to the elected invention, Applicants have reasonably demonstrated that for a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149 , or a cysteine at position 213 results in signal-enhanced glucose detection as evidenced by figure 1 and figure 8 of the

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instant application. However, the claims broadly encompass a group of amino acid substitutions for a mutated glucose binding protein which are clearly beyond the scope of the instant disclosure.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than using a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149 , or a cysteine at position 213 results in signal-enhanced glucose detection as evidenced by figure 1 and figure 8 of the instant application.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the Examiner acknowledges that representative examples of the claimed genus of mutant binding proteins are enabled and no undue experimentation is needed to practice the instant invention. However, the examiner contends that, other than using a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149 , or a cysteine at position 213 results in signal-enhanced glucose detection as evidenced by figure 1 and figure 8 of the instant application, claims 1, 3-7 and 12-13 broadly encompass a group of amino acid substitutions for a mutated glucose binding protein which are clearly beyond the scope of the instant disclosure. Claims 8-11 encompass site mutations 149 and 213, which are supported by the instant specification.

***Claim Rejections - 35 USC § 102***

Claims 1 and 3-13 are/stand rejected under 35 U.S.C. 102 (b) as being anticipated by Lakawicz (USPN 6,197,534) or by Hellinga (USPN 6,277,627) for the reasons of record which are restated below.

The instant invention is drawn to a biosensor comprising at least one mutated binding protein and at least one thiol group and at least one sensor surface which provides a detectable signal resulting from a change in refractive index when the mutated binding protein binds to analyte.

Each of the cited references teach a sensor comprising a modified glucose binding protein (see '534 patent, i.e., for example, claims 30, 32, 33, 34, 35, 37 38, and 40, columns 15 and 16 and '627 patent, i.e., for example, claim 1, column 11). Further, Hellinga ('627) discloses the glucose sensor of the invention and a glucose biosensor comprising a glucose binding protein (GBP) and a reporter group that transduces a detectable signal (see, i.e., for example, abstract and column 11, claim 1). Further, Lakawicz et al. ('534) expressly teach the protein is modified by substituting at least one cysteine residue (see, i.e., for example, claims 37 and 38, columns 15 and 16). Lakawicz discloses polymeric layers containing labeled glucose/galactose binding protein (see, i.e., for example, column 11, lines 53-54) and a modulation sensor, a glucose-sensitive probe combined with a probe of a metal-ligand complex( please note that such a complex reads upon a sensor surface) (see, i.e., for example, column 10, lines 39-41).

Applicant's arguments were carefully considered but were not found persuasive.

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Applicant contends that the present invention is directed to binding proteins coupled to a sensor surface capable of detecting binding of analyte by changes in refractive index. Applicant contends that the cited art fails to anticipate the instant invention as recited in claim 1 and its dependent claims. However, the examiner contends that Lakawicz ('534) discloses polymeric layers containing labeled glucose/galactose binding protein and a modulation sensor, a glucose-sensitive probe combined with a probe of a metal-ligand complex( please note that such a complex reads upon a sensor surface) and Hellinga ('627) discloses the glucose sensor of the invention and a glucose biosensor comprising a glucose binding protein (GBP) and a reporter group that transduces a detectable signal.

### NEW REJECTION

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakawicz (USPN 6,197,534) in view of Hellinga (USPN 6,277,627).

The instant invention is drawn to a biosensor comprising at least one mutated binding protein and at least one thiol group and at least one sensor surface which provides a detectable

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signal resulting from a change in refractive index when the mutated binding protein binds to analyte.

Based upon the beneficial overall teachings provided by Lakawicz in view of Hellinga with respect to a biosensor which provides a detectable signal resulting from a change in refractive index when the mutated binding protein binds to analyte, if not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make result effective adjustments in conventional working parameters thereto (e.g., providing a detectable signal from a change in refractive index) as a mere matter of judicious selection and routine optimization.

Thus, the claimed invention as a whole is *prima facie* obvious over the cited references, especially in the absence of evidence to the contrary.

### ***Conclusion***

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/8/05

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER